

## REMARKS/ARGUMENTS

Claims 1-8 are pending in the present application.

The Examiner has maintained the rejection of claims 1-8 under 35 U.S.C. §103(a) as being unpatentable over Dolitzky (WO 02/45658 and U.S. 6,924,393).

Claims 1-8, as presently amended, are directed to a process for preparing venlafaxine by converting N,N-didesmethyl venlafaxine of formula (I), a salt thereof, spiro venlafaxine of formula (II) or a salt thereof in the presence of a salt of formic acid in a specific molar ratio of the reactants to produce venlafaxine in solution, and then reacting the solution of venlafaxine with an acid to prepare an addition salt of venlafaxine.

According to the Examiner, the claims before the present amendment differ from Dolitzky, specifically Example 2 on Page 7 of WO 02/45658 by using different mole ratios of reactants. The Examiner, however, states that changing of reaction conditions such as reaction ratio is not patentable absent showing of criticality of the reaction conditions. The present amendment to the claims explicitly recites that the solution of venlafaxine produced in step a) is directly reacted with an acid to prepare an addition salt of venlafaxine. Because the venlafaxine that is produced in step a) under the process conditions recited in claim 1 is present in high yield and does not contain significant amounts of undesirable products, as noted in the present application at paragraph 25, there is no need to have a separate step of isolating the venlafaxine before reaction with an acid.

In contrast to the presently claimed process, the processes taught in Dolitzky for preparing the addition salt of venlafaxine are always preceded by the isolation of the venlafaxine free base. See, for example, Example 3 of U.S. Patent 6,924,393 in which *N,N*-didesmethyl venlafaxine is reacted with formic acid and the resulting solution is worked up to give crystalline venlafaxine base. The same process is also disclosed in Example 2 of WO 02/45658.

Neither U.S. Patent 6,924,393 or WO 02/45658 discloses or suggest that a solution of venlafaxine produced as recited in step a) of the present application can be directly reacted with an acid to prepare an addition salt of venlafaxine. Accordingly, it is respectfully requested that the rejection of claims 1-8 under 35 U.S.C. §103(a) as being anticipated by Dolitzky be withdrawn.

If any additional fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,  
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